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EXAMINER

RAJ, RAJIV J

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,032	Applicant(s) VANDERVEEN, TIMOTHY W.	
	Examiner RAJIV J. RAJ	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. This action is in reply to the amendment filed on 29 October 2008.
2. Claims 1-24 are currently pending and have been examined.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 17-24 are rejected under 35 U.S.C. 101 based on Supreme Court precedent, and recent Federal Circuit decisions, a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876). The process steps in claims (17-24) are not tied to a machine nor do they execute a transformation. Thus, they are non-statutory.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-7, 9-21, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halvorson (US 4847764) (hereinafter Halvorson) in view of Allen, III (US 4731726) (hereinafter Allen).
8. **Examiner's Note:** The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed

invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Claim 1

Halvorson as shown discloses the following limitations:

- *a plurality a plurality of medication administration devices for delivering medication to a plurality of patients; (see at least Halvorson Fig:2 Items:32,40,50-52 & related text)*
- *the medication administration information including a plurality of medication administration parameters and a parameter value associated with each medication administration parameter; (see at least Halvorson Fig:3 Items:62,63 & related text)*
- *a database operatively connected to the central processor for storing medication administration guidelines representing acceptable values for the medication administration parameters; (see at least Halvorson Fig:1 Items:10-32 Fig:4-23 & related text)*
- *means for communicating medication administration information from each of the medication administration devices to the central processor; (see at least Halvorson Fig:1 Items:10-32 & related text)*
- *wherein the central processor is further configured to compare the parameter values to the acceptable values for the parameters in the medication administration guidelines (see at least Halvorson Claim:2)*

Halvorson does not disclose the following limitations, however Allen, as shown does:

- *a memory associated with each medication administration device for storing medication administration information associated with the medication delivered to each patient, (see at least Allen Fig:2 Items:150-154 & related text)*
- *a central processor configured to receive medication administration information from each of the medication administration devices; (see at least Allen Fig:4 Items:10, 102-106 & related text)*

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson. One of ordinary skill in the art would have added these features into Halvorson with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 2

The combination of Halvorson/Allen disclose all the limitations of claim 1. Allen further discloses the following limitations:

- *a central computer display operatively connected to the central processor; (see at least Allen Fig:4 Items:10, 102-106 & related text)*
- *the central processor is further configured to display the medication administration information on the central computer display; (see at least Allen Fig:1 Items:12 fig:2 & related text)*

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 3

The combination of Halvorson/Allen disclose all the limitations of claim 2. Schlotterbeck further discloses the following limitation:

- *the central processor is further configured to provide a visual indication on the central computer display if one of the parameter values does not fall within the acceptable values for the parameter in the corresponding medication administration guideline (see at least Halvorson Fig:1 Items:10-32 & related text)*

Claim 4

The combination of Halvorson/Allen disclose all the limitations of claim 2. Schlotterbeck further discloses the following limitation:

- *the central computer display is located in a pharmacy; (see at least Halvorson Abstract, Fig:1 Items:10-32 Fig:16 Item:84 Fig:27 Item:92 Fig:28 Item:93 & related text)*

Claim 5

The combination of Halvorson/Allen disclose all the limitations of claim 3. Allen further discloses the following limitations:

- *means for a clinician to adjust the medication administration parameter values in response to the visual indication* (see at least Allen Column:6 Lines:45-50)

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 6

The combination of Halvorson/Allen disclose all the limitations of claim 5. Allen further discloses the following limitations:

- *means for the clinician to report to a caregiver at the point of care the adjusted medication administration parameter values* (see at least Allen Column:2 Lines:40-47)

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more

effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 7

The combination of Halvorson/Allen disclose all the limitations of claim 1. Allen further discloses the following limitation:

- *the central processor is further configured to automatically adjust the medication administration parameter values in response to an indication that one of the parameter values does not fall within the acceptable values for the parameter in the corresponding medication administration guideline*
(see at least Allen Fig:56 Items:320-370 & related text)

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 9

The combination of Halvorson/Allen disclose all the limitations of claim 2. Halvorson further discloses the following limitation:

- *means for communication between a caregiver located at one of the medication administration devices and a clinician located at the central computer display (see at least Halvorson Fig:1 Items:10-32 & related text)*

Claim 10

The combination of Halvorson/Allen disclose all the limitations of claim 1. Allen further discloses the following limitation:

- *the medication administration parameters include current medication administration device operating parameters; (see at least Allen Column:16 Lines:54-65 Fig:7A-8E & related text)*

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 11

The combination of Halvorson/Allen disclose all the limitations of claim 1. Allen further discloses the following limitation:

- *the medication administration guidelines include the acceptable values for the medication administration parameters based on patient condition data; (see at least Allen Fig:5G Items:320-370 & related text)*

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 12

The combination of Halvorson/Allen disclose all the limitations of claim 11. Halvorson further discloses the following limitations:

- *wherein the processor is further configured to compare the parameter values to the acceptable values for the parameters in the medication administration guidelines corresponding to the stored patient condition data associated with each patient* (see at least Halvorson Claim:2)

Halvorson/Allen does not disclose the following limitations, however Allen, as shown does:

- *a memory operatively connected to the central processor for storing patient condition data associated with each patient;* (see at least Allen Claim:5)

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method

and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 13

The combination of Halvorson/Allen disclose all the limitations of claim 12. Allen further discloses the following limitation:

- *the patient condition data for each patient includes current physiological status; (see at least Allen Fig:5B-F & related text)*

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 14

The combination of Halvorson/Allen disclose all the limitations of claim 1. Allen further discloses the following limitation:

- *the medication administration guidelines include the acceptable values for the medication administration parameters based on medication indication data; (see at least Allen Fig:6A-8B & related text)*

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Halvorson/Allen. One of ordinary skill in the art would have added these features into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 15

The combination of Halvorson/Allen disclose all the limitations of claim 1. Halvorson further discloses the following limitations:

- *a memory in which is stored medication order information for a plurality of patients, the medication order information including a plurality of prescribed medication administration parameters for delivering medication to each patient and a parameter value associated with each prescribed medication administration parameter; (see at least Halvorson Fig:3 Item:67 Fig:4, Fig:20 Item:85, Fig:25 Item:90 & related text)*
- *wherein the processor is further configured to compare the parameter values of the prescribed medication administration parameters to the acceptable values for the medication administration parameters in the medication administration guideline (see at least Halvorson Claim:2)*

Claim 16

The combination of Halvorson/Allen disclose all the limitations of claim 15. Allen further discloses the following limitation:

- *a central computer display operatively connected to the central processor and wherein the central processor is further configured to display the medication order information and the medication administration information on the central computer display (see at least Allen Fig:1 Items:12,14, Fig:2 & related text)*

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Halvorson/Allen. One of ordinary skill in the art would have added this feature into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 17

Halvorson as shown discloses the following limitations:

- *the medication administration information including a plurality of medication administration parameters and a parameter value associated with each medication administration parameter; (see at least Halvorson Fig:3 Items:62,63 & related text)*

- *storing a database of medication administration guidelines representing acceptable values for the medication administration parameters; (see at least Halvorson Fig:1 Items:10-32, Fig:4-23 & related text)*
- *communicating the medication administration information and the medication administration guidelines to a central location; (see at least Halvorson Fig:1 Items:10-32 & related text)*
- *comparing the parameter values to the acceptable values for the parameters in the medication administration guidelines; (see at least Halvorson Claim:2)*

Halvorson does not disclose the following limitations, however Allen, as shown does:

- *monitoring medication administration information associated with medication delivered to each patient (see at least Allen Claim:1)*
- *providing an indication at the central location if one of the parameter values does not fall within the acceptable values for the parameter in the corresponding medication administration guideline; (see at least Allen Fig:1 Item:10, Fig:2 Item:102, Fig:5G Items:320-370, Fig:6B Items:414-432, Fig:7A Items:500-516 & related text)*

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Halvorson. One of ordinary skill in the art would have added this feature into Halvorson with the motivation of providing an improved method and system for

monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 18

The combination of Halvorson/Allen disclose all the limitations of claim 17. Allen further discloses the following limitation:

- *displaying the medication administration information on a computer display at the central location* (see at least Allen Fig:1 Items:12 fig:2 & related text)

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Halvorson/Allen. One of ordinary skill in the art would have added this feature into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 19

The combination of Halvorson/Allen disclose all the limitations of claim 18. Halvorson further discloses the following limitation:

- *providing an indication at the central location includes displaying an alert on the computer display;* (see at least Halvorson Column:5 Lines:3-35, Fig:1 Items:10-32 & related text)

Claim 20

The combination of Halvorson/Allen disclose all the limitations of claim 17. Allen further discloses the following limitation:

- *adjusting the medication administration parameter values from the central location in response to the indication;* (see at least Allen Column:6 Lines:45-50)

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Halvorson/Allen. One of ordinary skill in the art would have added this feature into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 21

The combination of Halvorson/Allen disclose all the limitations of claim 17. Allen further discloses the following limitation:

- *communicating information from the central location to a care-giver located at the point of care* (see at least Allen Column:2 Lines:40-47)

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Halvorson/Allen. One of ordinary skill in the art would have added this feature into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more

effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 23

The combination of Halvorson/Allen disclose all the limitations of claim 17. Allen further discloses the following limitation:

- *the medication administration guidelines include the acceptable values for the medication administration parameters based on patient condition data* (see at least Allen Fig:5G Items:320-370 & related text)

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Halvorson/Allen. One of ordinary skill in the art would have added this feature into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 24

The combination of Halvorson/Allen disclose all the limitations of claim 17. Allen further discloses the following limitation:

- *the medication administration guidelines include the acceptable values for the medication administration parameters based on medication indication data;* (see at least Allen Fig:6A-8B & related text)

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Halvorson/Allen. One of ordinary skill in the art would have added this feature into Halvorson/Allen with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

9. Claims 8 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halvorson in view of Allen in further view of Kaufman et al. (US 5267174) (hereinafter Kaufman).

Claim 8

The combination of Halvorson/Allen disclose all the limitations of claim 1. Kaufman further discloses the following limitation:

- *the central processor periodically compares the parameter values to the acceptable values for the parameters in the medication administration guidelines throughout the administration of the medication* (see at least Kaufman Column:19 Lines:12-16)

It would have been obvious to one of ordinary skill in the art to add the feature of Kaufman into Halvorson/Allen. One of ordinary skill in the art would have added this feature into Halvorson/Allen with the motivation to provide an adjustable and a more

effective interactive medication delivery device. (see at least Kaufman Column:2 Lines:15-28)

Claim 22

The combination of Halvorson/Allen disclose all the limitations of claim 17. Kaufman further discloses the following limitation:

- *periodically comparing the parameter values to the acceptable values for the parameters in the medication administration guidelines throughout the administration* (see at least Kaufman Column:19 Lines:12-16)

It would have been obvious to one of ordinary skill in the art to add the feature of Kaufman into Halvorson/Allen. One of ordinary skill in the art would have added this feature into Halvorson/Allen with the motivation to provide an adjustable and a more effective interactive medication delivery device. (see at least Kaufman Column:2 Lines:15-28)

Response to Arguments

10. Applicant's arguments received on 29 October 2008 have been fully considered.

11. As per applicant's arguments regarding the 35 U.S.C. 101 rejection of claims 17-24, they have fully considered but they are not persuasive. The claim language of method claims 17-24 fail to tie the steps to any machine or transform underlying subject matter. Examiner respectfully disagrees with the use of *database* being a

machine, as required by 35 U.S.C. 101. Further applicant argues that the "*centralized monitoring of medication administration*" is a component of the invention, but Examiner respectfully disagrees pointing out that such language is in the preamble and does not impart the necessary criteria to overcome the 35 U.S.C. 101 rejection.

12. Applicant's arguments with respect to claim 1-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Rajiv J. Raj** whose telephone number is **(571) 270-3930**. The Examiner can normally be reached on Monday-Friday, 7:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Jerry O'Connor** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> <<http://pair-direct.uspto.gov>>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

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Date: 01/15/09
/RJR/ Patent Examiner Art Unit 3686

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